



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419
21254	7590	08/15/2005	EXAMINER	
MCGINN & GIBB, PLLC 8321 OLD COURTHOUSE ROAD SUITE 200 VIENNA, VA 22182-3817			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 5,8-12,15,17-27 and 30-34.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*Marjorie A. Moran*  
8/11/05  
**MARJORIE A. MORAN  
PRIMARY EXAMINER**

Continuation of 11. does NOT place the application in condition for allowance because Applicants' arguments are unpersuasive and the rejections are maintained

### 35 USC 112, 1st paragraph

It is noted that the header of this rejection in Applicant's after final amendment is mistakenly labelled as a 35 USC 112, 2nd paragraph rejection, when it is actually a 35 USC 112, 1st paragraph rejection. Applicants state that 35 USC 112, first paragraph, requires only that the specification "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." It is noted that 35 USC 112, first paragraph, also requires written description of the invention wherein all limitations of the instant claims are fully and completely supported by the specification, drawings, and claims, as originally filed. Applicants cite pages 12, line 24 to page 13, line 6 of the specification. Applicants state they have defined a gene portion in an exemplary aspect. It is noted that examples do not provide clear and concise definitions of a term or phrase. Applicants argue that one of skill in the art would assume and reasonably conclude that a portion other than a gene portion is a portion "which does not store a protein code sequence and transcription control information for said sequence". This statement is found unpersuasive as Applicants did not specifically state in clear and concise definitions what is and is not considered to be a genetic portion and other portion. Negative limitations must be fully supported by the original disclosure. And since there is a lack of clear and concise definitions, one of skill in the art would not know what to reasonably assume. One of skill in the art would be confused by the statement of "a portion wherein genetic information is not included" as stated in the specification on page 13, because by containing nucleotides automatically means it contains genetic information, in the broad and reasonable interpretation of "genetic information." Applicants argue that the Examiner failed to show that one of skill in the art would not know how to make and use the invention. This statement is found unpersuasive and confusing as the rejection set forth is a NEW MATTER, lack of written description, rejection and not an enablement rejection.

### 35 USC 103 rejection

Applicants argue that the prior art references would not have been combined and if combined the combination would not teach or suggest every element of the claimed invention. This statement is found unpersuasive as a motivational statement including the ability to track and the manufacture and distribution of natural resources was provided by Dollinger (col. 1, lines 17-20). Motivation and an expectation of success were provided in the rejection in the FINAL office action. Applicants summarize the Dollinger and Beremand et al. references. Applicants argue that the references would not be combined because they were directed to different problems. It is noted that the references need not be directed to the same problems, merely that there be a motivation to combine. Applicants argue that Dollinger has nothing to do with genes. This statement found unpersuasive as nucleic acids have something to do with genes, and these are described in the Dollinger reference. Furthermore, Dollinger describes the DQ-alpha allele, which is a gene. Applicants argue that Beremand is directed to a method of producing a synthetic gene and no person of ordinary skill in the art would have considered combining these references. Again, it is noted that motivation and expectation for success were discussed in the prior art rejection of the FINAL office action. Furthermore, Applicants have failed to provide any evidence or sound reasoning why this motivation or expectation of success would be considered improper.

Applicants argue that neither prior art reference teaches the limitations recited in instant claims 5 and 12 and similarly recited in instant claims 8, 11, and 15, particularly the highlighted limitations "embedded in said portion which is other than said gene portion" and "which identifies a source of said predetermined gene". Several portions of Dollinger stated in the FINAL office action will be reiterated to address these limitations. Dollinger describes a nucleic acid taggant which attaches to material (col. 1, lines 50-54) which represents embedding in said portion which is other than said gene portion. Dollinger describes the nucleic acids may be bound to solid support (devoid of genetic information) (col. 2, lines 23-26). Dollinger describes that nucleic acid may be covalently bound to any one or all components of a material comprised of different components (col. 2, lines 19-22) which represents embedding. Dollinger describes the nucleic acid taggant comprises specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of material (col. 1, lines 54-60 and col. 3, lines 7-8) which represents identifying a source and source identification information. Dollinger describes use of a taggant of a sequence complementary to the DQ-alpha (col. 6, lines 55-56) which represents information which identifies a source of said predetermined gene (DQ-alpha). Applicants argue that they have repeated arguments over and over and the Examiner continues to ignore Applicants' arguments. This statement is found unpersuasive as the Examiner has responded to arguments. The claims are written broadly and have therefore been interpreted broadly and reasonably. The lack of clear and concise definitions in the original disclosure justifies the practice of using broad and reasonable interpretations.

A. Applicants repeatedly pointed out that the taggant in Dollinger could not be considered a nucleotide sequence. This statement is completely confusing as describes nucleic acids which are by definition a nucleotide sequence. Nucleic acids are made up of nucleotides. More than one nucleotide is a nucleotide sequence. Applicants argue that the taggant of Dollinger is not embedded in DNA. It is noted that instant claim 5 does not state "embedded in DNA". Instant claim 5 recites "embedded in said portion which is other than said gene portion". It is noted that in the broadest reasonable interpretation of this phrase, the embedding is in a portion other than said gene portion which does not have to be DNA. Applicants argue that the taggant is applied to the barrel of radioactive waste with a spray bottle. That is merely one embodiment of the entire Dollinger reference which contains multiple embodiments. Applicants repeatedly argues that the nucleotide sequence is embedded in DNA. Applicants are advised to carefully read their claim limitations and read them broadly so that they understand that instant claim 5 does not state "embedded in DNA". Line 3 of claim 5 states "a portion" which could be anything in the universe that is not a gene portion. Nowhere does it state that this portion is DNA. If Applicants do not want the claims to interpreted so broadly, it is recommended that they narrow down their claim language with limitations supported by the original disclosure. Applicants argue about the embedding issue. It is noted that Applicants did not specifically define "embedded" which is therefore interpreted in a broad and reasonable manner. It is further noted that the Beremand et al. reference used in the 35 USC 103 rejection involves constructing, cloning, and use of expression vectors which involve embedding.

Applicants argue that the "material" in Dollinger to which the nucleic acid is covalently bound to is clearly not DNA. It is reiterated that claim 5 doesn't state "embedded in DNA". Applicants argue that Dollinger does not teach or suggest embedding a nucleotide sequence in a particular portion of DNA. It is noted that instant claim 5 does not specifically teach or suggest such embedding either. Applicants argue that Dollinger does not teach or suggest embedding a nucleotide sequence in a portion of DNA which is other than a gene portion of DNA. It is noted that instant claim 5 does not specifically teach or suggest such embedding either. Applicants are advised to carefully read their instant claims with broad and reasonable interpretations of the limitations.

B. Applicants argue that they have repeatedly pointed out that the taggant in Dollinger is not used to identify the source of said predetermined gene. This statement is found unpersuasive as Dollinger describes use of a taggant of a sequence complementary to the DQ-alpha allele (col. 6, lines 55-56) wherein the taggant represents the allele or predetermined gene DQ-alpha. Dollinger describes the nucleic acid taggant comprises specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of material (col. 1, lines 54-60 and col. 3, lines 7-8) which represents identifying a source and source identification information. Applicants argue that the Dollinger taggant is applied to a material to identify a source of the material such as a nuclear power plant. It is noted that Dollinger contains multiple embodiments of which the nuclear power plant is just one. Dollinger also describes the DQ-alpha allele (gene) and other source identification information (in above sentences) which read upon the instant claim limitations. Applicants argue that the nucleotide sequence identifies a source of the predetermined gene and that Dollinger facilitates "determining the origin or source of a material". It is noted that Dollinger describe a predetermined gene, DQ-alpha, and using a taggant complementary to it. Dollinger describe nucleic acids used as taggants allows for subsequent identification of a substance (col. 1, lines 11-16 and 25-27). It is noted that DQ-alpha allele is a substance. It is further noted that the Beremand et al. reference involves constructing, cloning, and use of expression vectors which involve embedding of nucleotide sequences, a laboratory practice that the person of ordinary skill in the art knows has been used for decades.

Applicants argue that it would be completely unreasonable and absurd to suggest that a taggant used to identify a source of non-living material could teach or suggest a nucleotide sequence which is embedded in a non-gene portion of DNA and identifies a source of a gene in the gene portion of that DNA. This statement is found unpersuasive for many reasons. First, instant claim 5 does not specifically recite the limitation "embedded in a non-gene portion of DNA". This interpretation is reading extra limitations into instant claim 5 that simply aren't there. Nor does instant claim 5 specifically state "identifies a source of a gene in the gene portion of that DNA". Third, it is noted that "non-living material" is not stated in instant claim 5. Regardless, Dollinger describes living organisms contain unique nucleic acids sequences (also called nucleotide sequences) that are either naturally or artificially introduced (col. 2, lines 65-67). Dollinger describes tracking animals and plants (gene bearing organisms) (col. 1, lines 17-19) which are living things and sources of genes.

Applicants argue that the Examiner concedes that Dollinger does not teach or suggest a predetermined gene. This statement is found unpersuasive and incorrect. It is noted that Dollinger do not teach a gene portion including a predetermined gene comprising a protein code.

Applicants summarize the Beremand et al. reference and argue that Beremand et al. do not describe embedding a nucleotide sequence in a non-gene portion of the DNA molecule to identify the source of the ACP gene. It is noted that instant claim 5 does not specifically recite a non-gene portion of DNA, but rather "portion which is other than said gene portion" which can be anything in the universe other than the gene portion. There is no recitation of DNA in line 3 of instant claim 5. It is also noted that a single reference does not need to contain all of the limitations of the instant claims in a 35 USC 103 rejection. (This is not a 35 USC 102 rejection.)

Applicants' arguments are deemed unpersuasive. If an interview is desired, they may call the Examiner.